A RANDOMISED TRIAL TO STUDY THE EFFICACY OF TWO OFFLOADING DEVICES IN THE MANAGEMENT OF PLANTAR DIABETIC FOOT ULCERS

Dissertation submitted to

THE TAMIL NADU DR. MGR. MEDICAL UNIVERSITY

In partial fulfillment of the degree of

M.S. GENERAL SURGERY

Branch – 1

PSG INSTITUTE OF MEDICAL SCIENCE AND RESEARCH

DEPARTMENT OF GENERAL SURGERY

APRIL 2014

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "**A RANDOMISED TRIAL TO STUDY THE EFFICACY OF TWO OFFLOADING DEVICES IN THE MANAGEMENT OF PLANTAR DIABETIC FOOT ULCERS**" is a bonafide and genuine research work carried out by me under the guidance of **Dr. VIMAL KUMAR GOVINDAN**, M.S., Professor, Department of General Surgery, PSG Institute of Medical Sciences, Coimbatore.

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CERTIFICATE BY THE GUIDE

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ACKNOWLEDGEMENT

I wish to thank our Principal for having permitted me to conduct this study in this hospital.

I am ever so grateful to the HOD and the entire faculty of the Department of Surgery for the kind guidance, valuable advices, supervision and encouragement while doing this study.

My thanks are also to my colleagues for the considerable help extended to me.

I wish to place on record my gratitude to all the patients who have been an integral part of this study. I am indebted to them for their willing participation.

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Introduction

Diabetes related peripheral neuropathy is a major etiological factor in the development of neuropathic foot ulcers. Repeated trauma and pressure on the ulcer bed are the two main reasons for persistence of ulcer.

Offloading allows for pressure relief at areas of high pressure thus facilitating healing process of foot ulcers. It is suggested that "Pressure relief on ulcers commonly referred to as offloading should always be a part of the treatment plan" Cavanagh et al (2005)

Aims and Objectives

The objective of this study is to compare the effectiveness of removable (custom made shoes) and irremovable (total contact cast) devices to offload plantar diabetic ulcers. The following aspects of offloading are looked upon:

1) wound surface areas reduction
2) number and severity of adverse events

Materials and Methods

Diabetic foot ulcer patients who have been admitted or have visited PSG hospital on OP basis were included in the study. 32 of these patients, who met inclusion and exclusion criteria of the study, formed the study population. After a detailed history, examination and necessary investigations, ulcers were surgically debrided to remove non viable tissues. Ulcers were photographed and measured and offloading devices were applied. Patients were advised 2 weekly follow-up for the next 3 months. The outcome was studied based on ulcer size reduction and the presence or absence of adverse events.

Results

A total of 32 patients were included in the study. Two patients in the TCC group and one patient in the custom made shoe group failed to complete the study. The ulcer surface area decreased from 6.82 cm^2 - 1.34cm^2 in TCC group and from 5.86 cm^2 - 2.23 cm^2 in custom made shoe group. Higher proportions of patients were healed by 12weeks in TCC group when compared to custom made shoe group. (1.34cm^2, P value=0.0154, Vs 2.23cm^2, P value=0.0016). Eleven out of the sixteen patients (68.7%) in TCC group had achieved complete healing with 90days of

treatment, of which 5 patients healed between 42 to 70days and three out of the thirteen patients (23%) had attained complete healing in custom made shoe group at the end of 12 weeks. The mean number of days for the ulcer to heal in the TCC group was 66.63 days whereas in the custom made shoe group it was 83.23 days which infers that the mean duration of healing time was less with TCC than with custom made shoes.

Conclusion

TCCs are gold standard in offloading diabetic foot ulcers with high proportion of healing rates in lesser amount of time compared to custom made shoes.

Keywords: Diabetes melliteus, neuropathy, plantar ulcers, off-loading, Total contact Cast

INTRODUCTION

INTRODUCTION

Diabetic neuropathic ulcers are the most frequent form of ulcers in the foot[1]. These ulcers are the major determinant of diabetes-related amputations of lower extremity[1]. About 85% of all the amputation in diabetes is mostly preceded by an ulcer[1].

Excessive pressure on sole of these neuropathic feet is the cause for developing these ulcers. The key to effective healing of these ulcers is to provide complete relief of pressure (off-loading) at the site of theses ulcers[2]. 'Offloading is a pivotal but often ignored and neglected aspect of wound care'- highlighted by Lavery (2003).

Along with pressure relief, surgical debridement of the ulcer and adequate dressing of the wound is essential for the complete healing of these ulcers[3]. Compliance of patients is generally poor as these patients lack any symptoms due to sensory neuropathy and tend to wear off-loading device very rarely[4].

Hence, a multidisciplinary team is needed which includes physicians for strict diabetic control, surgeons in assessment of wound condition and need for

debridement, podiatrist in assessing neuro-ischemic status of foot and a technician in off-loading of the ulcer. This team approach helps in effectively treating diabetic foot wounds.

The treatment most commonly employed in pressure reduction at the ulcer site of the foot are either a removable therapeutic shoe or an irremovable total contact cast[5].

Therefore the purpose of this study was to compare effectiveness of removable and irremovable off-loading device to heal neuropathic foot ulceration in diabetic patients.

Aims and Objectives

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The objective of this study is to compare the effectiveness of removable (custom made shoes) and irremovable (total contact cast) devices to offload plantar diabetic ulcers. Also the following aspects of offloading are looked upon:

1) wound surface areas reduction
2) number and severity of adverse events

Review of Literature

Review of Literature

History

1.1 History of Diabetes

Diabetes mellitus is one of the many common diseases known to affect the mankind from antiquity[6]. Its history started approximately in 1550BC[7]. An ancient literature of Egyptian medical journal has recorded it as a disease causing the patient to lose weight rapidly "Too great emptying of urine" [7].

Indian physician at the same time identified the sweetness of urine by noting that the urine would attract ants and classified it as madhumeha or "honey urine" [7]. It is the Greeks (Apollonius of Memphis) in 230BC who termed it "diabetes" or "to pass through" [7]. The word "mellitus" comes from Latin word meaning sweetened with honey. It was in 1675 when Thomas Willis added mellitus to the word diabetes as a designation for the disease[7].

Other historic milestones in diabetes are as follows:

- Greek physician Aretaeus of Cappadocia in 2nd century AD noticed the excess amount of urine being passed through the kidneys also was able to distinguish between Diabetes Melliteus and Diabetes insipidus[8].

- Aretaeus and Galen Roman physician attributed development of Diabetes to weakness of kidneys and called it "diarrhea of urine" (diarrhea urinosa) [9].

- 5th century AD, Sushrutha and Charaka, two Indian physicians differentiated between two types of diabetes: Type1 diabetes is seen in youths and Type2 diabetes in obese individuals[8].

- An important milestone in history of diabetes is establishment of role of liver in glycogen and the fact that diabetes is due to excess glucose production – Claude Bernard in 1857 [10].

- Avicenna (980-1027)AD gave good description of diabetes and its complications and diabetic gangrene[8].

- Mathew Dibson (1713-1784) proved the sweetness of urine is due to sugar and established sweetness of serum as hyperglycemia. He suggested that diabetes mellitus is a systemic disease[9].

- Pyrce (1887) described association of foot ulcer, neuropathy and vascular disease with diabetes mellitus[11].

- In 1900, the exact link between pancreas and diabetes was established [11.]

- Charles Best and Fredrick Banting (1922-1936) discovered insulin from pancreas[12].

- Able (1926) prepared crystalline insulin.

1.2 History of diabetic foot ulcer

Foot ulceration is the most common and disabling complication of diabetes mellitus. From ancient days, diabetes is a disease characterized by wide range of complications of which foot ulceration can lead to significant disability including lower extremity amputations[13.]

Between 1850 and 1870, plantar ulcers and gangrene were recognized as complications of Diabetes[11]. In 1798, John Rollo noticed that diabetic patients had difficulty in using their limbs due to pain and paraesthesia of lower limbs[11].

In earlier days all cases were described as "diabetic gangrene".

- Nitch in 1923 regarded it as senile gangrene due to arteriosclerosis[11].
- Rose and Carless, a decade later recognized the etiology as peripheral neuritis and endarteritis.
- Aird in 1957 identified the importance of infection in young patients.
- In 1893, a distinction was found between gangrene due to vascular insufficiency and gangrene due to infection in a limb with normal blood supply.

During this time, the only treatment was major amputation of the limb even if the area of gangrene was small [11].

It was regarded that diabetic foot occurred as a result of infection and pressure necrosis of soft tissue which was compressed between callosity of the sole and head of metatarsal bone leading to poor wound healing [14]. Also some patients had clawing of foot where the metatarsal heads showed abnormal descent and toes had become hyper extended. 60% of patients with previous ulcer history have chance of developing another ulcer over the same area because the skin over the healed ulcer site will be less resilient to accept repetitive stress. Hence they are more prone to subsequent ulcer[15].

1.3 History of treatment of diabetic foot ulcer

In yester years, the final outcome of complications of diabetic foot was invariably amputation[16]. Even now the cause for inpatient occupancy in diabetic patients is due to foot problems rather than the any other medical complications of diabetes[16]. Before the Second World War, the gangrenous changes in diabetic foot were considered due to a single cause and later, only in 1893; a distinction was found in

gangrene due to vascular insufficiency and gangrene due to infection in a limb with normal blood supply[11].

Diabetic foot ulcer healing seems to be arrested at inflammatory or proliferative process, causing infection and inflammation. Many years ago honey was used in dressing of diabetic foot ulcer[17]. It was found that the anti inflammatory action of honey would decrease the excess activity of collagenase and elastase which are seen in inflammatory condition. It was observed that honey promotes tissue regeneration by stimulating angiogenesis and growth of fibroblasts and epithelial cells[17].

For the past 40 years, the concept of moist wound healing of diabetic ulcers has been accepted.

The various types of moist wound dressing are:

Calcium alginate dressings: These are dressings derived from seaweed available as sheets to pack deep wounds. The exudates from the wound and calcium alginate form a gel. These are used for moderate to heavy draining wounds.

Collagen dressings: These are used for moderate to heavily draining wounds to enhance healing and tissue repair. These have been found useful on burns, pressure ulcers and dermatologic conditions.

Foam dressings: They are made of hydrophilic polyurethane foam, and offer a moist environment and cushion the wound.

Hydrocolloid dressings: These are soft wafers which become gel like when in contact with wound exudates. They are waterproof and impermeable to bacteria and dust.

Hydrogels: They hydrate tissue and facilitate debridement using the body's own enzymes. Because of high water content, there is limited drainage.

2. Extent of the problem

2.1 Globally

It has been estimated that, the number of people having diabetes mellitus worldwide was 131 million in 2000 and it is projected to increase to 366 million by 2030 [18]. 4%-10% of pts with diabetes have a risk of developing foot ulcer at anytime in their life[19]. The annual incidence of diabetic foot ulcer is about 3% and the incidence in U.S and U.K ranges as 10% [20]. Lower extremity diseases affect 30% of diabetic persons who are older than 40 years[21]. Peripheral arterial disease, peripheral neuropathy, foot ulceration, or lower extremity amputation, is twice as common in diabetic persons compared with non-diabetic persons[21]. Almost 40% of this amputation can be avoided if there is a team approach to care of diabetic wound. The incidence of amputation can be reduced if the incidence of diabetic foot ulcer reduces. 20% of diabetic patients with foot ulcer have peripheral arterial disease about 50% have peripheral neuropathy and 30% will have a combination of both[22]. The estimated costs of treating a diabetic foot ulcer were $28,000 in a 1999 US study[23], and $18 000 (with no amputation) and $34 000 (with amputation) in a 2000 Swedish study.[24]

2.2 India

India has the largest diabetes population in the world. More than 50million people are diagnosed to have diabetes. 85% of amputated cases have found to have diabetes as the causal factor. The prevalence of amputation is about 3%. In India the prevalence of diabetic foot complications like neuropathy is 15%, peripheral vascular disease is 5% and infections is 7.6%. 55% of foot ulcers are neuropathic, 35% are neuroischemic and 10% are ischemic. Diabetic foot ulcers cause a huge amount of emotional, physical, productivity and financial losses[25].

Pathogenesis of diabetic foot ulcer

Patients with diabetes have 12-25% lifetime risk of developing a foot ulcer[26]. People with diabetes mellitus develop foot ulcer due to neuropathy (sensory, motor, and autonomic), ischemia or both[27]. Hence these ulcers are classified into neuropathic, ischemic, or neuroischemic. But there is a complex interplay between these factors and other etiological factors like increased foot pressures, limited joint mobility, poor glycemic control, and cardiovascular parameters[27]. Hence

identifying these high risk patients and educating them will help us in reducing the incidence of foot ulcerations and amputations[27].

Diabetes mellitus primarily affects the vessels & nerves causing vasculopathy and neuropathy.

Vasculopathy

Atherosclerotic vascular disease is present in subclinical form in diabetic patients with long duration[27]. One of the earliest steps in the pathogenesis of atherosclerosis is the binding of monocytes, leukocytes, and platelets to the endothelium which is promoted by adhesion molecules. Such adhesion molecules are seen to be elevated in diabetes[28]. Peripheral vascular disease was found to be 2.5 to 3 times commoner in diabetic than nondiabetic patients[29].

Peripheral vascular disease in diabetes mainly effects the vessels between knee and ankle (infra popliteal) leading to poor perfusion of tissues causing friable tissues [27]. Thus a mechanical damage to these tissues leads to development of ischemic ulcers. In 38-52% of ulcers, ischemia is the major etiological factor and 46% of amputations are due to ischemia[30]. Thus any form of injury leads to increased

requirement of blood supply which cannot be met leading to ischemic ulcerations and risk of amputation follow[30].

Neuropathy

The incidence of neuropathy is equal to the duration and severity of hyperglycemia. Patients with neuropathy are at 1.7times greater risk for ulceration compared to patients without neuropathy[31].

Causes of neuropathy:

There are 2 theories to causation of diabetic peripheral neuropathy. First, a metabolic factor has been hypothesized as the cause, and the other its association with micro vascular disease. Therefore a nerve biopsy in diabetic neuropathy shows both focal nerve fiber loss along with ischemic injury.

Pathophysiology of diabetic neuropathy[32,33]

1) Hyperglycemia – increased levels of intraneural sorbitol and fructose which is toxic to the tissues.

2) Hyperosmolality causing edema of nerves.
3) Reduced myoinositol- impairs action of Na- K ATPase and altered myelin synthesis.
4) Occlusive vasanervorum

Effects of neuropathy:

Neuropathy affects the foot both extrinsically and intrinsically.

1. Extrinsic neuropathic foot ulceration

Due to loss of somatic sensation over the plantar aspect of the foot, the patient is unable to perceive the normal painful stimulus. The patient's perception of touch, deep pressure, temperature and joint position is impaired. Thus a continuous tissue-damaging excess mechanical load to an insensate foot leads to ulcer formation[34,35].

2. Intrinsic neuropathic foot ulceration

Somatic motor neuropathy leads to weakness of intrinsic muscles of foot, leading to abnormal movement of small bones of the foot along with joint subluxation[27]. There is also weakness of foot ligaments due to abnormalities of collagen

metabolism. Visceral sensory neuropathy leads to reduced proprioception and the patient continues to walk. The ligaments and joint capsule are further stretched and bony structure of foot is distorted leading to deformities like claw foot with prominent metatarsal heads, or rocker-bottom foot with collapse of longitudinal arch and prominence of tarsal bones. These bony changes produce areas of localized high pressure in the sole of the foot mainly metatarsal heads, tips of toes and heel[35]. It initially responds to the high pressure by forming a protective callus and a continued shear force traumatizes the underlying subcutaneous tissue producing cavities containing blood or serum. Finally the callus breaks down resulting in an ulcer[35]. The typical feature of neuropathic ulcer is that there will be deep tissue destruction before the epithelial breakdown.

Other risk factors for development of foot ulcers include:

1) Previous foot ulceration: Foot ulcers are more common in those patients with a past history of ulceration or amputation and in patients with a poor social background.

2) Diabetes duration and control: Poor glycemic control as measured by HbAlc, fasting blood glucose, and even single random blood glucose is strongly predictive of subsequent amputation[36].

3) Delayed wound healing: In diabetic patients, the process of wound healing is slow and this increases the susceptibility to infection and finally predisposes to amputation[37]. In diabetic patients, neutrophil function is impaired leading to abnormalities in phagocytosis and killing ability[37].

Characteristics of diabetic foot ulcer

Diabetic foot ulcers are most commonly seen over the bony prominences and on the heel. Diabetic foot ulcers are classified into two, ischemic and neurotrophic based on their ulcer characteristics. This classification is important in selecting the appropriate treatment of ulcer.

1) Ischemic ulcers: The ulcer has punched out necrotic areas with sharp margins. During debridement there will be bleeding from the periphery. There will be severe pain which is exacerbated during nights. Relief from pain is obtained on hanging the legs down. Prognosis for healing is poor. Treatment includes meticulous foot care and to control risk factors.

2) Neurotrophic ulcers: These are caused by pressure on the weight bearing areas. The ulcer has granulation surrounded by hyperkeratotic tissue. Good vascular supply is present so the foot is often warm. Callus with bony deformities do occur.

Classification system for Diabetic Foot Ulcers

Wagner's Classification for Diabetic Foot Ulcers

Grade	Lesion
1	Superficial diabetic ulcer
2	Ulcer extension involving, ligaments, tendon, joint capsule, or fascia with no abscess or osteomyelitis
3	Deep ulcer with abscess or osteomyelitis
4	Gangrene to portion of fore foot
5	Extensive gangrene of foot

University of Texas Diabetic Wound Classification System

Stage	**Grade**			
	0	**I**	**II**	**III**
A (no infection or ischemia)	Pre or post ulcerative lesion completely epithelialised	Superficial wound not involving tendon, capsule or bone.	Wound penetrating to tendon, capsule or bone.	Wound penetrating to bone or joint.
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia

Treatment of diabetic foot ulcer

The main principle of neuropathic diabetic foot ulcer includes controlling of infection and to remove the pressure from the ulcer[38].

Strategies for saving the diabetic foot include[38]:

1) Tight glycemic control
2) Identifying etiological factors
3) Assessment of vascular status
4) Management of infection
5) Offloading strategies
6) Multidisciplinary team approach
7) Patient education

Glycemic control

Adequate glycemic control is the most vital in healing of diabetic foot ulcers. It has been found that leukocyte function is impaired in patients with chronic hyperglycemia leading to delay in wound healing of established foot ulcers[38].

Identifying the etiological factors

Foot ulcers are commonly seen in 50% of patients more than 60years[39].

The cause for the ulcer, if due to peripheral neuropathy or peripheral vascular disease must be identified. Other causative factors include repetitive trauma, self

inflicting trauma while cutting toe nails, history of previous foot ulcers and excessive plantar pressure due to foot deformities[39].

Basic examination of foot helps to determine the neuro-vascular status of the foot.

Assessment of vascular status

Palpation of foot pulses (Dorsalis pedis and posterior tibial artery) would be part of the initial examination.

If pulses are feeble or not palpable, vascular investigations are done to evaluate the extent of vaso-occlusion and to assses the healing potential of foot ulcer[40].

These include:

1) Doppler study (Duplex scanning with ultrasound analysis)
    - To measure segmental systolic pressure
    - To provide flow velocity wave form.
    - To study the location and amount of lumen occlusion.

2) Ankle-Brachial pressure index[40]

The higher systolic pressure at the ankle is divided by the brachial pressure to give ankle-brachial pressure index (ABPI). Low values are obtained when there is a complete occlusion and high values when there are very minimal atheromatous changes. If there is a constant decrease in ABPI means there is an advancing disease and a constant rise in ABPI indicates development of collaterals.

3) Toe Pressure

Toe pressure measurement is reliable in assessing the healing potential of an ulcer. Transducers are inserted in the sole of footwear to assess the toe pressure. In toe pressure >40mmhg, ulcers heal well. If pressure <20mmhg healing is doubtful[41].

4) Transcutaneous oxygen tension (TcPO2)

Transcutaneous oximetry can be used to measure the arterial oxygen supply. >30mmhg - good healing, <10mmhg – non-healing[42.]

5) Digital subtraction angiography (DSA)[43]

Vessels are visualized using digital fluorography technique for image enhancement.

Advantage:

- DSA accomplishes significantly better contrast resolution.
- Highly sensitive screening technique for carotids and lower limb vessels.
- When compared to conventional angiography, cost is less.
- DSA can be performed routinely on OP basis.
- DSA may demonstrate small reconstituted vessels distal to an obstruction not seen on a catheter cut-film study.

An ideal angiography should answer 4 vital questions:

1. The site and extent of the stenosis / occlusion.
2. The 'Run-in' state of arteries proximal to stenosis is normal or not?
3. The 'Run-off' Arterial bypass surgery is only feasible if a named distal artery is open beyond the block.
4. State of collateral circulation.

Neurological assessment of foot[44]

1. Monofilament test: Using 5.07 Semmes-Weinstein monofilament (10gm) wires for sensory examination.
2. Plantar pressure: Assessed using Harris mat and computer technique. Allows quantitative measurements of plantar foot pressure.
3. Two point discrimination
4. Vibration sense
5. Temperature sensation

Control of wound infection

Early identification of infection and its prompt management is crucial in preventing limb loss[45]. Almost 50% of diabetic patients with infected ulcer do not show the classical signs of infection due to poor blood supply that reduces the inflammation and redness and neuropathy that masks the pain[45]. The aim of antimicrobial therapy is to cure the infection and not to heal the wound. The antimicrobial treatment is selected empirically and then according to patients' response and based on culture and sensitivity reports the antibiotic regimen is modified. In ulcers with mild to moderate infection, oral antibiotics are sufficient. Topical antibiotics are also available for local application over the ulcer.

Sometimes infection of the ulcer can spread into the underlying bone causing osteomyelitis. This is treated by resection of all infected and necrosed bone and antibiotics that penetrate well into the bone[46].

Wound care

Initial management includes cleaning of the wound by removing the necrotic and dead tissues and probing the ulcer to check for presence of foreign bodies or to see if the bone is exposed[45].

Such sharp debridement of the wound enhances the healing of ulcer which includes removing of the callous using scalpel and forceps. Under aseptic precautions the pus aspirate should be obtained and sent for culture of micro organism and their sensitivity to various antibiotics is tested[45]. Plain x-ray of foot helps to find out presence of foreign body, gas in tissues or presence of osteomyelitis. Blood investigations are done to look for complete blood count, leukocyte differentiation, basic chemistry panel and ESR (erythrocyte sedimentation rate).

Removal of pressure

Elevated plantar pressure is a causative factor in the development of plantar ulcers in diabetic patients with sensory neuropathy[45]. Repeated trauma and excess mechanical load over the foot leads to non healing of diabetic foot ulcer. Therefore offloading of the ulcer site helps to prevent repeated trauma and facilitates wound healing. Techniques of removing pressure vary depending on various factors like: patient's preference and compliance and severity of ulcer

Patient education

Patent should be educated about good diabetic control, foot care, dangers of smoking etc. All diabetic patients should have an annual foot examination that includes assessing for anatomic deformities, skin breaks, nail disorders, loss of protective sensation, diminished arterial supply, and improper footwear.

Multidisciplinary Team approach

A team approach helps in prevention and management of diabetic foot problems.

Team member's include[45]:

1) Physician to educate about glycemic control.
2) Nurse educator to educate about foot care.
3) Podiatrist to detect and treat foot lesions
4) Surgeon for debriding the ulcer
5) Orthotist for offloading ulcers.
6) Vascular surgeon for revascularization procedures.

Off loading devices

Pressure relief on ulcers and redistributing it to the healthy areas is referred to as offloading[47]. This reduces the trauma to the ulcer site and allows healing. Neuropathic ulcers that resisted healing for months to years have healed on use of offloading devices[47].

Patients should never walk in the same shoes that lead to development of ulcers[48]. Bony deformity along with displacement of soft tissue in a neuropathic foot leads to elevated plantar pressure causing ulceration and failure to heal[48]. In a diabetic

person, claw toe deformity and charcot's neuroarthropathy are the abnormalities that can cause disruption of architecture of foot and elevated plantar pressure[48].

The use of offloading helps to prevent the repetitive trauma associated with walking which in turn helps in wound healing[4].(Amstrong et al 2003)

Offloading of diabetic foot ulcers can be achieved by using various removable and non removable devices[49].

Methods of offloading include[49]:

1. Total non weight bearing- bed rest
2. Total contact cast
3. Foot casts or boots
4. Removable walking braces with rocker bottom sole
5. Half shoes or wedge shoes
6. Accommodative dressing: felt, foam
7. Shoe cutouts
8. Assistive devices like crutches, walker, wheelchair etc.

Patient compliance is very important when using an offloading device as it is useful only when the patient wears it[50]. Hence the patient must be educated about the importance of the offloading device in order to improve the patient's adherence to offloading. Usually neuropathic patients do not wear their offloading device as they do not feel any pain. That is why total contact cast is considered the golden standard[50].

There are various factors that influence a patients desire to wear the device[51].

- Instability during the gait.
- Comfort of the device.
- Weight
- Cosmesis
- Ease of application

Removable walker Casts[52]

Removable walker casts are easy for the patient and the doctor as it can be removed to inspect the wound if infection is present. They are cost effective and

easy to apply. Removable walker casts are better to use when there is a soft tissue or bone infection because it can be removed to inspect the wound.

Advantages[52]:

- Easily removed for self inspection
- Easily removable for local application of therapies.
- Easy to daily activities
- Can be used for infected wounds
- Can be used for superficial wounds

Total Contact Casts (TCC)

This is the most common method of offloading used by doctors[53]. This method of offloading was first described by Milroy Paul[54]. TCCs have shown to reduce pressure at ulcer sites by 84-92%. Its healing rates range from 72%-100% over 5-7weeks[55]. TCC acts by reducing the pressure by transmitting this pressure along the cast wall or to the rear foot. Hence useful in treating fore foot ulcers[56].

Advantages of TCCs[57]:

- Protects foot from infection
- Helps in reducing edema

Disadvantages[58]:

- Technically difficult to apply need experienced persons
- Time consuming.
- Improper application causes skin irritation and ulceration
- Daily wound assessment cannot be done
- Difficulty in daily activities like bathing without wetting the cast
- Difficulty in sleeping
- Affect gait stability.

Contraindications:

- For wounds with ischemia
- For infected wounds
- For wounds with osteomyelitis

Half shoes[59]:

They are designed to decrease the pressure on the fore foot postoperatively.

Advantage:

- Removable
- Easy to apply – inexpensive

The key to successful pressure reduction lies in patient's adherence than in the offloading device that is prescribed.

MATERIALS AND METHODS

MATERIALS AND METHODS

Source of Data:

* All patients who have met the inclusion criteria, irrespective of their age or sex who come to PSG Hospitals, Coimbatore in the department of surgery/ diabetology/medicine with diabetic foot ulcer during the period of February 2012 to December 2013 were included in the study.

Method of Collection of Data:

The data for this study was collected from the 30 subjects fulfilling the inclusion/exclusion criteria, who came to PSG Hospitals attending Surgery OPD for Diabetic foot ulcer care during the study period February 2012 to December 2013, using a proforma specially designed for the study.

Sample size: 30

Study period: February 2012 to December2013

Inclusion criteria:

- Should have Type1 or 2 diabetes mellitus.
- Should have peripheral neuropathy[60] with a palpable foot pulse.
- Should have plantar ulcers for a period of at least 3weeks.
- Ulcers should be of Grade 1 according to Wagner's Classification[61].

Exclusion criteria:

- Patients with huge ulcers with size >4cm.
- Patients with more than one ulcer in the same foot.
- Peripheral vascular disease with ABPI<0.9
- Presence of clinical signs of infection- erythema, edema, increase local skin temp, secretions, fever, gangrene, maggots.
- Ulcer probing to the bone.

Collection of Samples:

30 random cases were selected from the study group either admitted in surgery wards or attending surgery OPD for Diabetic Foot Ulcer management. Cases were selected based on inclusion and exclusion criteria included in our study. Consent was taken from all the subjects.

Patients were randomized through a computerized randomization schedule into two different groups. In which Group A was off-loaded with a non-removable total contact cast, and Group B using Custom Made Shoes. Patients received specific instructions on how to manage the off-loading devices.

A proforma was developed to record the medical history and examination details. Medical history was taken for all the subjects. Details regarding type of diabetes, its duration, treatment, compliance and personal habits were recorded. Patients were assessed for peripheral polyneuropathy which was defined[60] as the absence of two of five sensory modalities (vibration sensation using the 128-Hz tuning fork, light touch, blunt-sharp discrimination, Achilles tendon reflex, and 10-g monofilament). Meticulous examination was done including description of the ulcer (site, size, shape and Grade 1 ulcers according to Wagner's Classification were included) as per the proforma of the study. Ulcers with hard callous or ulcers

containing slough were surgically debrided eliminating all non-viable tissues and the entire area of lesion exposed. Ulcers were photographed and traced on to a tracing paper or a graph paper and the surface area of the ulcer was measured and recorded. Following which the ulcers were dressed and covered with sterile dressing before applying the off-loading device.

Patients in Group A were casted with POP (Plaster of Paris) after positioning a layer of protective dressing over the ulcer site to avoid contact with the cast. Attention was given in avoiding friction or trauma with bony prominences by protecting them with extra layers of cotton. Rubber heals were placed to allow the patients to stand and walk.

Patients in Group B were given Custom Made Shoes, adapted according to the ulcer site and size and patients foot condition. Forefoot, midfoot and hind foot pressure relieving foot wears are prescribed according to ulcer site. All the shoes were made by the same podologists. All patients were instructed to wear the device at all times during ambulation.

Group A patients treated with Total Contact Cast

Picture of Total Contact Cast used to off-load ulcers over great toe

Picture of Total Contact cast used to off-load ulcers over mid foot

Group B patients treated with Custom made Shoes

Picture showing different types of shoes used to off-load ulcers at various sites

Follow up

Patients of both the groups were followed up biweekly for upto 90 days or to complete reepithelialization of the ulcer. At each checkup, patients in Group A had their cast removed. Lesions were debrided if needed, measured, photographed and dressed and a new cast was applied. Cast treatment was terminated when there was no reduction in wound size or depth during 4 consecutive weeks, when an infection greater than grade 2 developed, or when the patient had severe discomfort with the cast. These cases are all defined as cast failure [60]. The same procedure was carried out in Group B patients too. Presences of any adverse events were also recorded like discomfort, chafed skin, preulcerative lesion (defined as a non-ulcerative lesion related to local pressure in the cast), new ulcers on the affected foot, and lower-extremity joint problems and infective complications.

Outcome

The primary outcome was the rate of wound healing (complete epithelialization or healing at the end of 12weeks). Out of the 33 diabetic patients, 2 failed to complete the course of study. Reasons for this included discomfort, instability (two TCC-cast failures), or failure to return for follow-up appointments (one custom made shoe).

Observation and Results

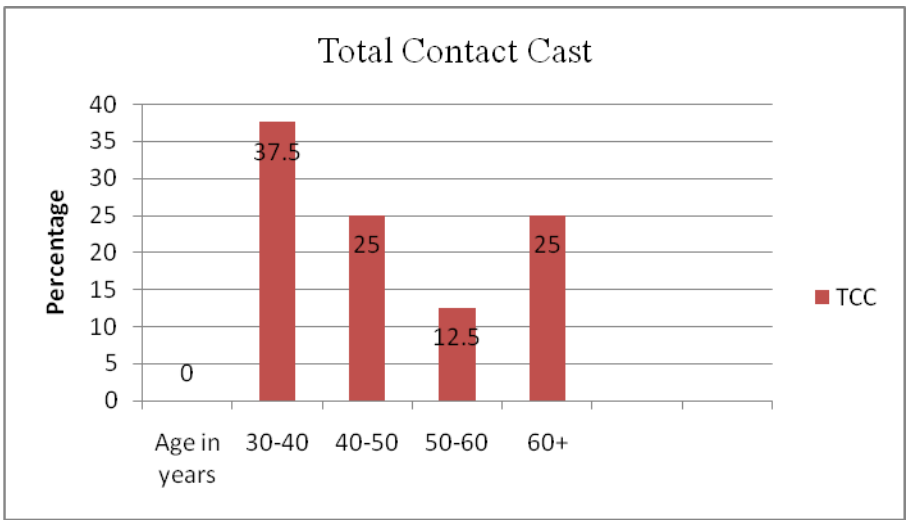
Observation and Results

Study Design: A randomized control study consisting of 32 patients with diabetic foot ulcers were undertaken to study the effect of removable and non-removable off-loading devices in healing of diabetic foot ulcers and its correlation with various clinical features.

Table 1: Age wise distribution of patients in the two study groups

	TCC		Shoe	
Age in years	**No. of patients**	**Percentage %**	**No. of patients**	**Percentage %**
30-40	6	37.50	1	7.69
40-50	4	25.00	5	38.46
50-60	2	12.50	4	30.77
60+	4	25.00	3	23.08
Total	16		13	

Graph 1: Age wise distribution in TCC



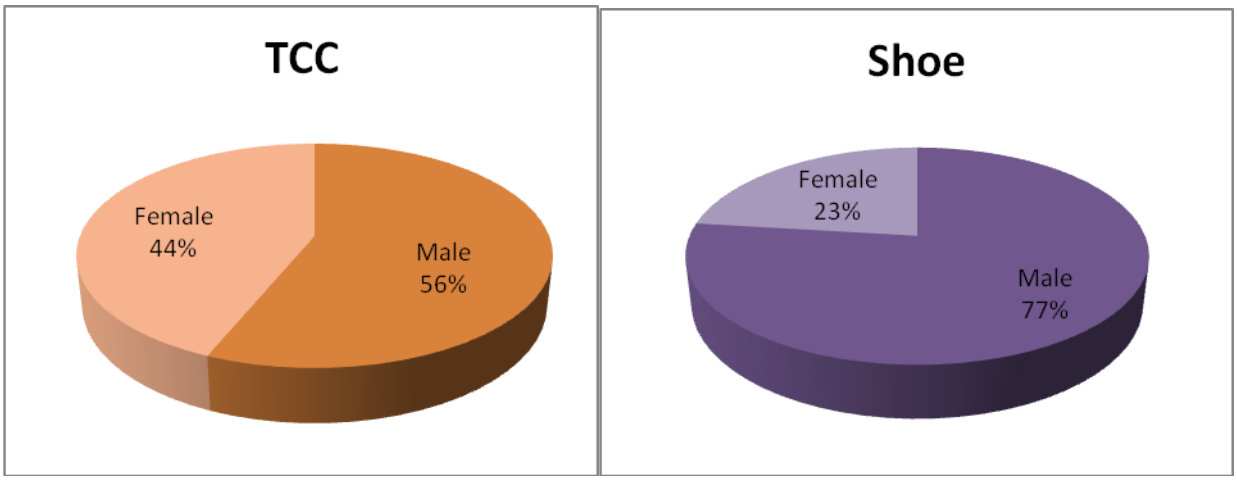
Graph 2: Age wise distribution in Custom-made Shoe

As shown in Table 1 & Graph 1 and 2, in the present study the age variation was from 34yrs to 68yrs. Majority of the patients were in the age group of 30-40yrs in patients with total contact cast which was 37.5% and age group of 40-50yrs in patients with custom made shoes which was 38.46%.

Table 2: Gender distribution of patients in the two study groups

	TCC		Shoe	
Gender	**No. of patients**	**Percentage %**	**No. of patients**	**Percentage %**
Male	9	56.25	10	76.92
Female	7	43.75	3	23.08
Total	16		13	

Graph 3 : Gender distribution

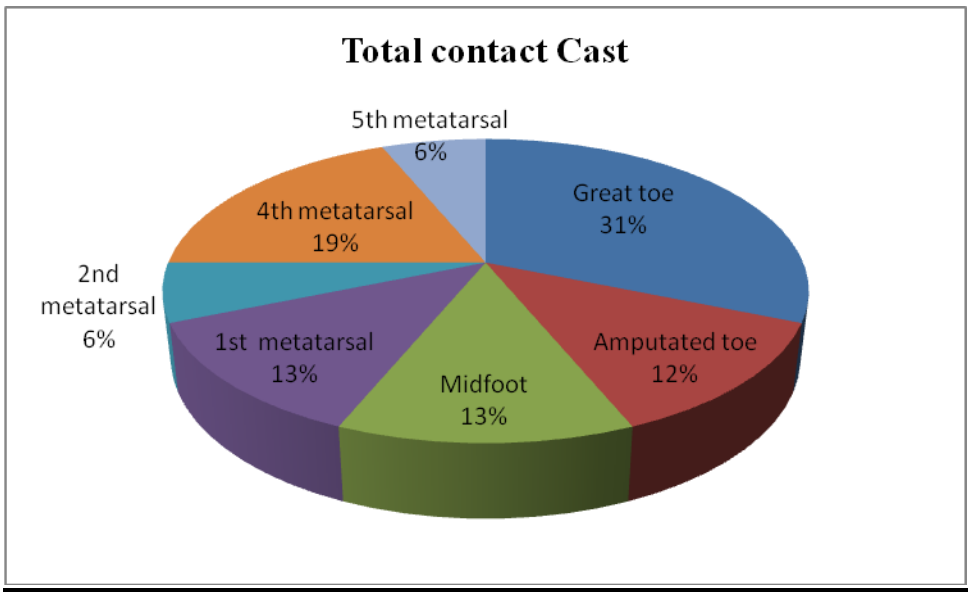


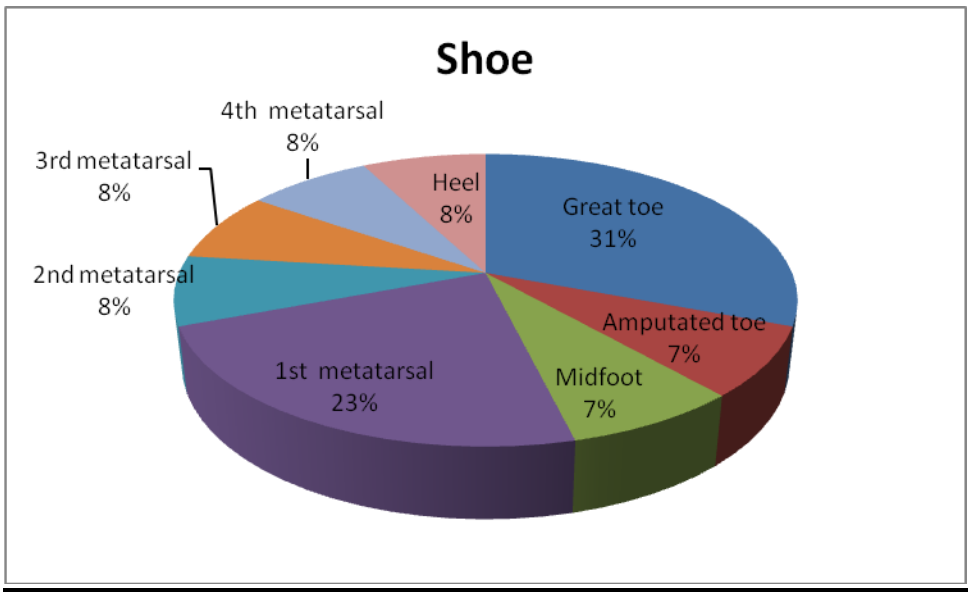
As shown in Table 2 & Graph 3, majority of the subjects in the 2 groups in the present study were **Males**(56% and 77%) as compared to females (44% and 23%).

Table 3: Distribution of sites of ulcers in patients of both study groups

	TCC		Shoe	
Site of Ulcer	**Number**	**Percentage**	**Number**	**Percentage**
Great toe	5	31.2%	4	30.7%
Amputated toe	2	12.5%	1	7.6%
Midfoot	2	12.5%	1	7.6%
1st metatarsal	2	12.5%	3	23%
2nd metatarsal	1	6.2%	1	7.6%
3rd metatarsal	-	-	1	7.6%
4th metatarsal	3	18.7%	-	-
5th metatarsal	1	6.2%	1	7.6%
Heel	-	-	1	7.6%

Graph 4 : Distribution of sites of ulcer





As shown in Table 3 and Graph 4, majority of the ulcers were seen over the plantar aspect of great toe in both the groups.

Picture showing various sites of Ulcers

2nd metatarsal head

1st metatarsal head

4th metatarsal head

Heel

Results

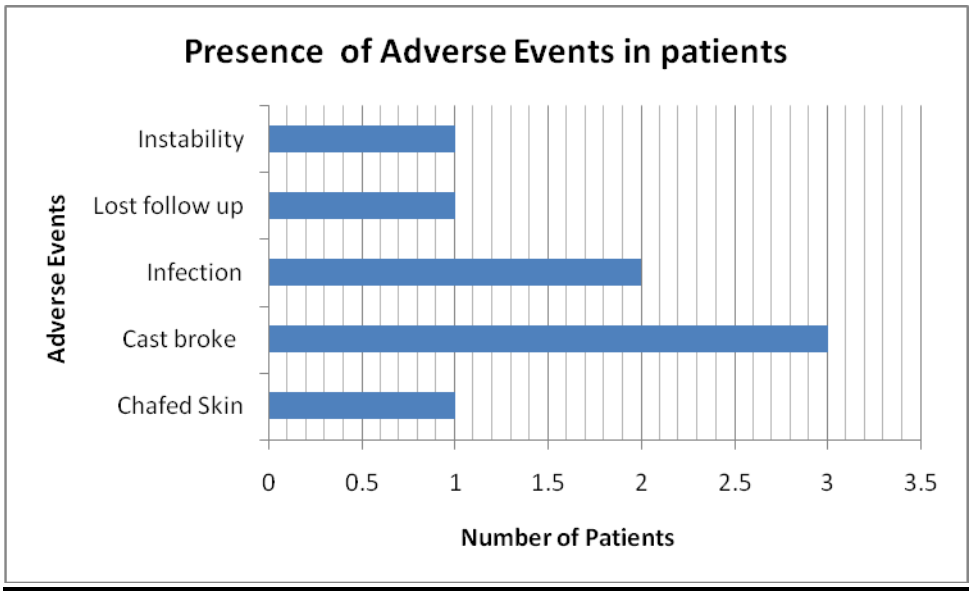
Results

A total of 32 patients were included in the study. Two patients in the TCC group and one patient in the custom made shoe group failed to complete the study. Of these three dropouts, one patient in TCC group developed pre-ulcerative lesion and chafed skin and was not willing for further treatment. The second patient, also in the TCC group, developed discomfort in the cast with instability to walk and breakage of cast, and hence withdrew from the study. One patient in shoe group developed Grade 2 infection which required further debridement and patient lost follow up.

S.No	Adverse Events in TCC	Treatment
1.	Chaffing of skin	Adequate padding prior to applying the cast.
2.	Breakage of cast	Cast was reapplied
3.	Discomfort in the cast with instability to walk.	

S.No	Adverse Events in Shoe	Treatment
1.	Grade 2 infection	Minimal debridement and administration of oral antibiotics for 7 days

Graph 5: Adverse events that occurred in both study groups



Of the remaining 29 patients who completed the study, there were 16 patients in the TCC group and 13 patients in the custom made shoe group. Some minor treatment complications had developed during the study period but none of them required termination of treatment or any change in treatment and were improved

within the subsequent visits. One patient in the TCC group developed minimal chaffing of skin which was relieved by adequate padding prior to applying the cast. Another patient had breakage of cast during treatment and cast was reapplied. In the shoe group, two patients had developed Grade 2 infection which needed minimal debridement and administration of oral antibiotics for 7 days. In both the cases the signs of infection had resolved within 1 week and infection did not recur. The patients continued their study.

The Table 4 below shows characteristics of the patients.

Table 4: Descriptive characteristics in the two study groups

	TCC		Shoe		
Variables	**Mean**	**SD**	**Mean**	**SD**	**P Value**
N	16		13		
Age	47.63	10.94	52.00	13.68	0.3466
Male %	56.25		76.92		
Duration of Ulcer (months)	11.06	9.35	5.62	4.37	0.064
Duration of DM (months)	102.06	70.12	60.54	57.79	0.0982
Ulcer Size at each visit	**Surface area of Ulcer (cm^2)**				
• Initial visit (0 Day)	6.82	4.47	5.86	2.57	0.4961
• After 14 Days	5.08	3.52	5.29	2.75	0.8616
• After 28 Days	3.60	2.91	4.70	2.96	0.3228
• After 42 Days	2.96	2.11	3.86	2.72	0.355
• After 56 Days	2.03	1.76	3.50	2.63	0.1128
• After 70 Days	1.44	1.52	2.74	2.38	0.1373
• After 90 Days	1.34	1.33	2.23	2.10	0.4118
No. of Days for Ulcer to Heal	**66.63**	22.36	**83.23**	14.46	0.0288

There were no significant differences between the two groups in the characteristics evaluated like age, sex and duration of diabetes. The healing time was not influenced by age, sex or duration of diabetes.

Eleven out of the sixteen patients (68.7%) in TCC group had achieved complete healing with 90days of treatment, of which 5 patients healed between 42 to 70days and three out of the thirteen patients (23%) had attained complete healing in custom made shoe group at the end of 12 weeks.

Table 4 also shows that the mean number of days for the ulcer to heal in the TCC group was 66.63 days whereas in the custom made shoe group it was 83.23 days which infers that the mean duration of healing time was less with TCC than with custom made shoes.

Table 5:Comparative Change in Ulcer Size Between the Two Study Groups

No. of Days	TCC			Shoe		
	Ulcer Size(cm^2)	P Value[1]	P Value[2]	Ulcer Size(cm^2)	P Value[1]	P Value[2]
0 Day	**6.82**			**5.86**		
14 Days	5.08	0.2303	0.2303	5.29	0.5932	0.5932
28 Days	3.60	0.0218	0.2036	4.70	0.2991	0.6036
42 Days	2.96	0.008	0.514	3.86	0.0663	0.4578
56 Days	2.03	0.0012	0.2358	3.50	0.033	0.7385
70 Days	1.44	0.0008	0.393	2.74	0.0046	0.4674
90 Days	**1.34**	0.0154	0.9022	**2.23**	0.0016	0.5995

P Value[1]: Comparing each measurement day with the 0 day/baseline

P Value[2]: Comparing each measurement day with its previous measurement

Table 5 shows that the ulcer surface area decreased from 6.82 cm^2 - 1.34cm^2 in TCC group and from 5.86 cm^2 - 2.23 cm^2 in custom made shoe group. Higher proportions of patients were healed by 12weeks in TCC group when compared to custom made shoe group. (1.34cm^2, P value=0.0154, Vs 2.23cm^2, P value=0.0016).

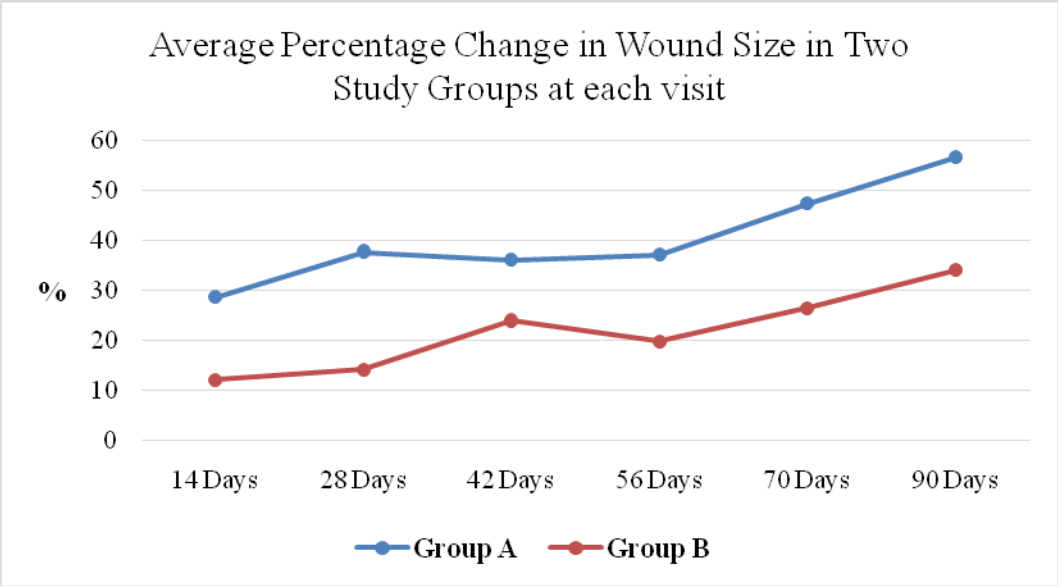
The time taken for the ulcer to heal was directly proportional to the area of the ulcer at the time of off-loading. Small ulcers (<3cm) took less than 90days to heal, compared to larger ulcers which took 90days or more for the ulcer to heal.

Table 5: Percentage Reduction in Wound Size at Each Visit in the Two Study Groups

	TCC		Shoe		
Percentage Change in Wound Size after	**Mean**	**SD**	**Mean**	**SD**	**P Value**
14 Days	28.76 %	14.69	12.22 %	13.55	<0.01
28 Days	37.81%	22.52	14.26 %	15.64	<0.01
42 Days	36.13%	12.50	24.08 %	19.37	0.0716
56 Days	37.17 %	17.28	19.91 %	9.81	<0.01
70 Days	47.51 %	20.58	26.54 %	16.13	0.0124
90 Days	56.72 %	16.59	34.14 %	14.43	0.0173

In this table we have calculated the average percentage reduction in size of the ulcer at every 2 weeks and the graph below shows the average percentage reduction.

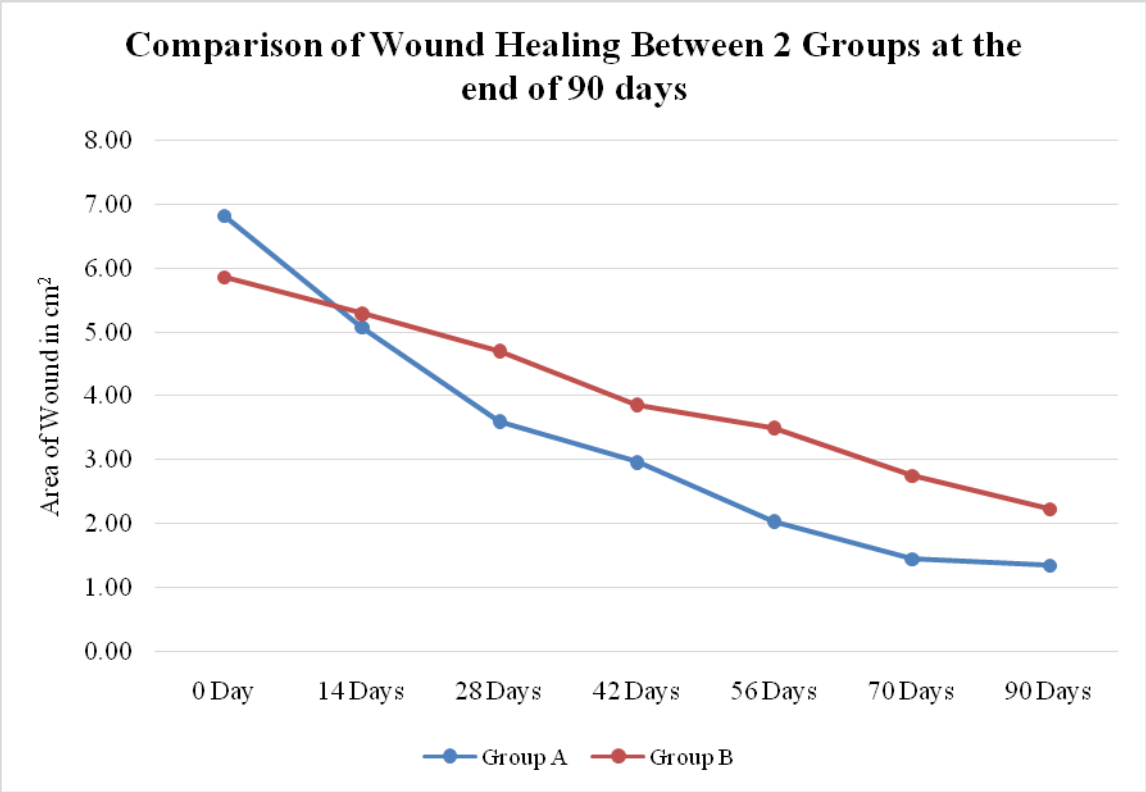
Graph 6: Comparison of average percentage reduction in ulcer size at each visit in the two study groups



Group A: TCC, Group B: Shoes

In our study it was also noticed that there was a faster reduction in size of the ulcer over the first 4weeks (28days) in patients treated with TCC and that after 4 weeks, the ulcer size reduction was almost similar in both the groups.

Graph 7: Comparison of wound healing at end of study



Group A: TCC, Group B: Shoes

This graph above depicts the ulcer size reduction at the end of study completion between patients treated with TCC and custom made shoes. This graph also shows that there was a significant reduction in the size of ulcers during the first four weeks in patients treated with TCC following which the healing time was almost same in both the groups. P value=0.0154 (TCC), P value=0.0016 (Shoe).

Pictures Showing Reduction in size of the ulcer over the plantar aspect of great toe during treatment with Total Contact Cast

On Day 0

After 70 days

Pictures Showing complete re-epithelialization of the ulcer over the plantar aspect of mid foot after treatment with Total Contact Cast

Picture 1

Picture 2

- Picture 1 showing the size of ulcer after 2 weeks of treatment with Total Contact Cast (14^{th} day)
- Picture 2 showing complete re-epithelialization of the size of ulcer after 90days of treatment with Total Contact Cast.

Pictures Showing Reduction in size of the ulcer over the plantar aspect of head of 1st metatarsal during treatment with Custom made Shoes

DISCUSSION

DISCUSSION

The intent of this study was to compare the ability of removable and irremovable devices to effectively offload diabetic neuropathic ulcers. Two aspects of offloading were looked upon:

1) wound surface areas reduction

2) number and severity of adverse events

The period of this study was from February 2012 to October 2013. Diabetic patients with neuropathic plantar ulcers were included in this study. These patients were randomly divided into two groups, those with the irremovable Total Contact Casts (TCC) and those with removable custom made shoes. Both the study groups were explained about the advantages and disadvantages of the treatment. There were various difficulties faced while convincing these patients to get enrolled into the study. Patients planned for TCC were not willing for treatment initially as most of these patients were laborers and did not want anything that will restrict mobility. Some patients found difficulty in driving, whereas some patients found treatment to be expensive i.e. application of totally 6 POPs. Patients in custom made shoes were explained about the importance of wearing the shoes throughout,

but only few patients adhered to these instructions. Majority of the patients developed recurrent trauma or infection of the ulcer which required wound debridement, hence leading to further increase in size of these ulcers.

Comparing the acceptability between the two groups, it was found that patients were more easily acceptable with custom made shoes compared to TCC as it had these advantages.

1. Patients were able to enjoy their daily life activities like bathing, sleeping.
2. Shoes could be used for infected wounds and self inspection of wound was possible.

In our study, among the 32 cases of diabetic foot ulcers, who were enrolled, 29cases were studied, which included 16 patients in TCC group and 13 patients in custom made shoe group. Majority of the subjects in the 2 groups were males (56% and 77%) as compared to females (44% and 23%) and were mostly of the age group 30-40 years (37.5%) in TCC group and of 40-50yrs (38.46%) in Custom made shoe group. All the patients included in our study were of Diabetes Mellitus Type II. All the patients included in our study had Wagner's Grade I diabetic foot ulcer.

Studies have shown that plantar pressures are highest in the forefoot and less towards the rear and medial arch[62]. In the present study, majority of the neuropathic foot ulcers were seen over the plantar aspect more towards the forefoot than in other areas of the foot. Highest percentage of ulcers (31%) were seen over the great toe in both TCC and shoe groups.

Antonella et al (2002) study showed that the forefoot-to-rear foot (F/R) plantar pressure ratio is higher in patients with severe peripheral neuropathy[63]. This increased F/R plantar pressure ratio causes the forefoot to be more loaded with pressure than rear foot, leading to the development of equinus deformity which is the main causative factor for development of diabetic foot ulcers. His study also showed that highest pressures points were commonly seen along the metatarsal heads.

Increased biomechanical stress is most crucial in leading to ulceration in patients with neuropathic foot ulcers[51]. In diabetic patients, due to advanced glycation of soft tissues, there occurs a functional shortening of Achilles tendon. This combined with motor impairment and rupture of plantar fascia may cause equinus deformity or foot drop, and therefore leading to increased pressure load on the plantar aspect.

Patients with diabetes also have sensory neuropathy with reduced proprioception[35]. The ligaments and joint capsule are further stretched and bony structure of foot is distorted leading to deformities like claw foot with prominent metatarsal heads. These bony changes produce areas of localized high pressure in the sole of the foot mainly metatarsal heads, tips of toes and heel[35]. It would therefore seem reasonable to assume that reduction of this stress would promote healing. Hence, offloading of diabetic foot ulcer is the treatment for neuropathic diabetic foot ulcers.

Shaw *et al* in their study noticed that peak plantar pressures seen in the forefoot were remarkably reduced by the use of TCC when compared to Shoes or barefoot walking. TCC achieves forefoot unloading by various mechanisms[62], two of which are:

1. Almost 30% of weight from the leg is directly transmitted to the cast wall.
2. TCC removes the load bearing surface from the metatarsal heads by the cavity by the soft foam covering the fore foot.

The result of this study shows that the ulcer surface area decreased from 6.82 cm^2 - 1.34cm^2 in TCC group and from 5.86cm^2 - 2.23cm^2 in custom made shoe group

(TCC: 1.34cm^2, P value=0.0154, Vs Shoe: 2.23cm^2, P value=0.0016). This suggests that the non-removable TCCs heal a higher proportion of wounds by 12 weeks compared to removable Custom made shoes. Hence, we can say that the success of offloading is strictly related to the non removability of the device used. In this present study it was also noticed that there was a faster reduction in size of the ulcer over the first 4weeks (28days) in patients treated with TCC and that after 4 weeks, the ulcer size reduction was almost similar in both the groups.

Hence, it could be suggested that diabetic patients with plantar neuropathic ulcers could start their off-loading with TCC and then switched over to custom made shoes, if they wished.

Earlier studies by, Armstrong *et al* (2005) have shown that the rate of healing of neuropathic diabetic ulcers at 12weeks is greater than 80% in patients treated with irremovable devices, while it reduced to less than 60% in patients treated with removable devices[51]. Since diabetic neuropathic ulcer patients have an insensate foot and do not feel the pain, they tend to walk without the removable shoe which adds to the lack of compliance. A study by Armstrong *et al* (2003) showed that

there was an increase in the number of footsteps and activities in patients with removable shoes off than footsteps with removable shoes on[50]. This revealed that patients were incompliant with removable device. Hence non removable casts are superior over removable devices[50] because of the fact that patients cannot remove the TCC and they take less active when using it. Armstrong *et al* (2003) study also noticed that though the patients with removable shoes were advised to wear the shoes continuously, patients wore them only for 28% of their footsteps[52]. In our study, most of the patients in the custom made shoes group, admitted to the fact that they wore the shoes only during outdoor activities. It therefore emphasizes the point that effective counseling is necessary prior to starting the treatment with custom made shoes.

It was also seen that patients with TCC had reduced repetitive stress to the ulcer as it was completely covered. This was not the case with custom made shoes, because the wounds were open. A few patients developed wound infection, which required debridement, thereby further leading to increase in size of ulcer and increased healing time. This in turn explains the success of TCC over Custom made shoes.

Apart from the ability to mitigate pressure, TCCs have several advantages. TCCs due to its complete coverage protect the wound from infection. TCCs help to

control edema[57]. The most important point for TCC is its ability to "force compliance" in patients. Patients using TCC are forced to use the cast all throughout as the device cannot be removed easily without the clinician's orders. Thus TCC is indeed the better choice to offload neuropathic diabetic plantar ulcers.

There were also several limitations of TCC[64] that were reported, such as new ulcers may develop in the cast at areas of friction of skin with the cast, and the inability of patients and clinicians to assess wound daily. All clinicians do not have an experienced technician to apply a cast correctly as improper application can cause skin irritation or ulceration. Mobility of patients is impaired which affects the daily activities like bathing and sleeping. Costs of treatment with TCC may be high as compared to Custom made shoes which are one time expenditure[64]. TCCs are contraindicated in patients with soft tissue infections.

Conclusion

The main treatment of diabetic neuropathic, non-infected, non-ischemic ulcers is proper debridement and pressure reduction over the ulcer.

In conclusion, this study suggests that based on the different offloading devices selected there is a significant difference in healing of diabetic foot ulcers.

TCCs are gold standard in offloading diabetic foot ulcers with high proportion of healing rates of 68.7%. Eleven out of the sixteen patients achieved complete healing with 90days of treatment, of which 5 patients healed between 42 to 70days

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Proforma

Patient Identication:

Date: Time: Height: Weight:

1. Describe the reason for the visit?
2. History of present illness / wound status:
    - When the wound was first noticed?
    - How did the wound start?
    - How do you clean your wound?
    - What do you use for a dressing change?
    - How often do you change your dressing?
    - What previous treatments have you had for the wound?
    - Did any previous treatments help your wound?
    - Does the wound cause you pain?
    - If so describe the pain on a scale: at its worst_____ at its best_____
    - When you have pain how long does it last?
    - When does the pain occur most often?
    - What makes the pain worse?
    - What makes the pain better?
    - Do you have any other symptom with the pain?

1. Medical history: _____

2. Past hospitalizations

Date	Reason for hospitalization
_____	_____
_____	_____

3. Current medications:

Medication	Dose/How often
_____	_____
_____	_____
_____	_____

4. Allergies

	Reaction:
_____	_____
_____	_____
_____	_____
_____	_____

Allergy to rubber or latex containing products?

5. Habits:

Tobacco use: Type____How much_____how many years_____Quit?

Alcohol use: Type_____How much_____how many years_____Quit?

Illicit drug use: Type_____ How much_____how many years_____Quit?

6. Diet: Special diet/ diet restrictions:
   _____

7. Family history:

Diabetes Heart problem Stroke Cancer Leg ulcer

8. Social history:

- Marital status _____
- Who do you live with?_____
- Occupation?_____
- Who changes your dressing?_____

EXAMINATION at each visit:

Any new complaints:_____

Wound assessment:

- Location :
- Wound etiology:
- Size(cm): L____ x B_____
- Photo:
- Painful: Yes No
- Wound color:
- Fibrous tissue:
- Granulation tissue
- Necrotic tissue
- Margins: wnl macerated
- Edema : No Yes
- Erythema: No Yes
- Odour:
- Drainage:

- Pulses:

Dorsalis pedis: R:____, L:_____

Popliteal : R:____, L:_____

Femoral: R:____, L:_____

- Deep tendon reflexes:
- Sensations: vibratory sensation proprioception
- Lymphatics:
- Labs / Imaging results:

Assessment:

_____

Treatment Plan:

- Wound assessed: Yes ( ) No ( )
- Wound cleaned: Yes ( ) No ( )
- Patient/family education: Yes ( ) No ( )
- Sharp debridement: Partial thickness ( )
  Full thickness ( )
- Anaesthesia type: Yes ( ) No ( )
- Neuropathic : Yes ( ) No ( )

- Dressings / cast / device / shoe gear:
  _____

- Wound care orders:
  _____

- Procedures/ diagnostic tests ordered:
  _____

- Others:
  _____

- Treatment:
  _____

- Next visit: 1week 2week 3week 4week

- Others: _____

Physician's signature and date:
_____

Master chart TCC Group

Case no:	Age	Sex	Ip / Op no:	Duration of ulcer	Rt/Lt Foot	Grade of ulcer	Duration of DM	Site of ulcer	Size of original ulcer (cm2)	Size of ulcer after 14days	Size of ulcer after 28days	Size of ulcer after 42days	Size of ulcer after 56days	Size of ulcer after 70days	Size of ulcer after 90days	Adverse events
1	42	M	O12080882	2 Months	Left	Grade 1	6years	Great toe	6.594	5.8875	4.90625	3.611	2.826	2.1195	0.785	Nil
2	38	M	O10069503	1year	Left	Grade 1	14years	5th metatarsal	3.2499	2.6376	1.0205	0.4396	0.1256	Healed		Nil
3	62	F	O10085225	1year	Right	Grade 1	14years	Midfoot	3.14	2.1195	0.6908	Healed				Nil
4	34	F	O13033211	4Months	Right	Grade 1	7Months	Amputated toe	2.00175	0.8635	0.11775	Healed				Nil
5	37	M	O13104110	1year	Left	Grade 1	2years	4th metatarsal	5.495	3.611	3.14	1.57	1.1775	0.4396	Healed	Nil
6	46	M	O10005857	2Months	Right	Grade 1	3years	Great toe	5.4165	3.611	2.826	1.76625	0.785	0.27475	Healed	Nil
7	60	F	i13035331	6Months	Left	Grade 1	11years	Midfoot	12.0576	9.2473	8.2425	7.065	6.123	5.0554	3.611	Chafed skin
8	34	F	O13068742	2Months	Right	Grade 1	6Months	Amputated toe	2.6376	0.942	0.2826	Healed				Nil
9	61	M	O97026339	1and1/2yr	Right	Grade 1	20years	Great toe	6.5312	4.12125	2.9673	2.2608	1.5386	0.628	Healed	Nil
10	32	M	O12047271	3Months	Right	Grade 1	8years	Great toe	5.8875	4.90625	2.53555	1.53075	0.785	Healed		Nil
11	62	M	O13033573	2years	Left	Grade 1	5years	1st metatarsal	10.99	9.61625	6.86875	4.87485	4.082	1.53075	0.4396	Nil
12	58	M	O00018359	3months	Right	Grade 1	12years	2nd Metatarsal	9.891	7.85	6.0445	4.71	2.47275	1.3188	0.471	Nil
13	58	M	O13055648	6months	Left	Grade 1	5years	4th metatarsal	2.94375	2.34715	1.53075	0.785	0.5652	0.1256	Healed	Nil
14	56	F	O97054527	1year	Right	Grade 1	12years	4th metatarsal	7.51245	5.8875	3.5325	2.2608	1.0205	0.5024	Healed	Nil
15	46	F	O13033197	1and1/2yr	Left	Grade 1	7years	1st metatarsal	5.495	3.925	2.826	1.53075	1.0205	0.628	Healed	Nil
16	62	F	O13076171	8months	Right	Grade 1	16years	Great toe	19.311	13.7375	10.048	6.08375	3.925	3.2499	1.413	Cast broke

Master chart Shoe Group

Case no:	Age	Sex	Ip / Op no:	Duration of ulcer	Rt/ Lt Foot	Grade of ulcer	Duration of DM	Site of ulcer	Size of original ulcer (cm2)	Size of ulcer after 14days	Size of ulcer after 28days	Size of ulcer after 42days	Size of ulcer after 56days	Size of ulcer after 70days	Size of ulcer after 90days	Adverse events
1	45	F	O13011204	6months	R	Grade 1	1year	1st metatarsal	8.2425	7.41825	5.8875	4.51375	3.9564	2.9673	1.209	Nil
2	55	M	i13000064	1month	L	Grade 1	2years	Mid foot	9.06675	8.2425	7.7715	6.594	5.5107	4.8984	3.454	Nil
3	49	M	O13045009	3months	R	Grade 1	5month	Great toe	3.14	2.6847	2.00175	1.413	0.8635	0.3768	Healed	Nil
4	52	M	O11006649	3months	R	Grade 1	6years	Great toe	6.123	5.29875	4.6629	3.925	3.13215	2.2608	1.413	Nil
5	51	M	O07067976	2months	R	Grade 1	13years	1st metatarsal	5.1025	4.12125	3.9721	2.983	2.669	2.669	2.002	Nil
6	60	M	O01003487	1year	R	Grade 1	5years	2nd metatarsal	3.14	3.297	3.925	3.72875	2.669	1.7663	1.531	Infection
7	47	M	O12056782	9months	L	Grade 1	2years	1st metatarsal	9.42	7.693	6.86875	6.0288	4.51375	2.9673	2.12	Nil
8	74	M	O19094110	7months	R	Grade 1	1year	Great toe	5.495	4.3332	3.13215	1.884	1.53075	0.785	Healed	Nil
9	68	M	O01008334	1month	R	Grade 1	3years	Great toe	1.53075	0.942	0.628	0.11775	Healed			Nil
10	48	M	I13019653	1year	R	Grade 1	10years	Heel	9.61625	11.304	12.2303	10.7467	10.7388	9.2944	7.787	infection
11	68	M	O07064837	4months	R	Grade 1	14years	3rd metatarsal	5.652	5.495	3.768	3.14	2.512	1.9782	1.099	Nil
12	45	F	O13033197	1year	R	Grade 1	8years	Amputated 5th toe	4.90625	4.15265	3.14	2.4021	1.76625	1.5308	0.785	Nil